K092391

Concord Medical Products

APR - 1 2010

510(k) Summary

Submitter's Name and Address

Concord Medical Products
87 Cambridge St
Burlington Ma 01803

Contact Person:

Randall Fincke
781-257-5172
Fax 781-998-0524

Date Prepared:

July 20, 2009

Device Name

Common or Usual Name: Automated External Defibrillator (AED)
Device Name: MobileAED, MobileALS, MobileAED+, and AdvantageAED

Classification

Defibrillator Low energy DC Class II LDD (21 CFR 870.5300)
Automatic External Defibrillators; Class III MKJ (AED) (21 CFR 870.5310)
Cardiac Monitor (Cardiotachometer and Rate Alarm) Class II DRT (21 CFR 870.2300)

Device Description

The MobileAED is a Biphasic AED which is a portable battery operated semi-automatic low power DC defibrillator. The device's ECG analysis algorithm analyzes the patient's cardiac rhythm to determine if a shockable versus non-shockable ECG rhythm is present. The operator follows the device instructions and presses the shock button to deliver a defibrillation shock.
The MobileAED and AdvantageAED product features include a Status Indicator, Graphic Display, Voice Messages, Buttons for Power and Shock, ECG algorithm analysis, Biphasic truncated exponential waveform, Lithium Manganese Dioxide Battery, and disposable Pads for defibrillation.

The MobileALS manual control features include Energy selection button, Charge button, Analysis button, and Sync button

Substantial Equivalence

The MobileAED and AdvantageAED products included in this submission are substantially equivalent with regard to the performance, safety and effectiveness, to other legally marketed semi-automatic low power DC defibrillators. These predicate devices include Medtronic PhysioControl LifePak 500, Cardiac Science Powerheart G3, Zoll AED Pro, and Philips Heartstream FR2+. The MobileAED and AdvantageAED products have the same general indication for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate devices. Differences between these products and the predicate devices do not raise new questions of safety or efficacy.

Indication for Use

The Concord Medical Products MobileAED, MobileALS, MobileAED+ and AdvantageAED products are designed for emergency treatment of cardiac arrest by trained personnel to terminate potentially fatal arrhythmias. The user assesses the patient's condition and confirms that the patient is unconscious, absence of a pulse or signs of circulation and has an absence of normal breathing prior to use of the device.
When the patient is a child or infant, up to 8 years of age or up to 55 lbs (25Kg), the Concord Medical Pediatric Defibrillation Pad which attenuates the energy should be used. Therapy should not be delayed to determine the patient's exact age or weight.

The Concord Medical Adult Pad should be used for patients over 8 years old and over 55 lbs (25Kg).

The MobileALS and MobileAED+ products are the same as the MobileAED with an option to provide manual control for defibrillation for use by advanced cardiac life support (ALS) users.

The rescuer may use the ECG monitoring mode cable feature to provide a non-diagnostic ECG rhythm display of a breathing or responsive patient regardless of age. Connection of the ECG monitoring mode cable disables the defibrillation feature and allows ECG analysis either in background or by pressing the analyze button.

Contraindications for Use – Defibrillation

Do not use the MobileAED for defibrillation when the patient;

Is conscious; or
Is breathing; or
Has a detectable pulse or other signs of circulation

Comparison of Technological Characteristics

The MobileAED and AdvantageAED products have features and functional characteristics similar to those of the indicated predicate devices. These products analyze the patient ECG and advise the operator with visual and audible prompts to assess the patient status, perform CPR or deliver a shock. The optional ECG monitor cable and manual controls are substantially equivalent to the Zoll AED Pro and Philips Heartstart FR2+ defibrillators.

Performance Data

The performance and safety test data demonstrate that the device meets all of its functional and performance specifications and complies with FDA guidelines and industry standards including the applicable sections of AAMI DF80, IEC 60601-1, IEC 60601-2-4 standards.

Conclusion

Test data demonstrate that the safety and effectiveness of the features and functions in the MobileAED and AdvantageAED products with the Biphasic waveform is substantially equivalent to the listed predicate devices with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR - 1 2010

Concord Medical Products
c/o Mr. Randall Fincke
President
87 Cambridge Street
Burlington, MA 01803

Re: K092391
Trade/Device Name: MobileAED, MobileALS, MobileAED+, and AdvantageAED
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillators
Regulatory Class: Class III (three)
Product Code: MKJ, LDD, DRT
Dated: February 10, 2010
Received: March 2, 2010

Dear Mr. Fincke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

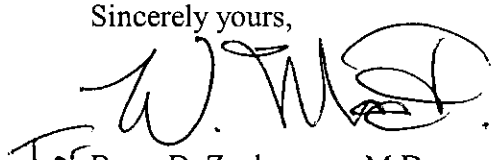
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): __ K092391_____

Device Name: MobileAED, MobileALS, MobileAED+, and AdvantageAED

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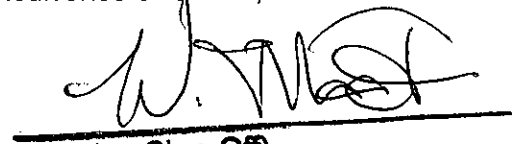
Prescription Use _X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

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